NDA 21-521/ IND 58,495
PREXIGE (COX189, lumiracoxib 100 mg tablets)

Regulatory History

Significant Date	Submission or meeting Type	Details
May 24, 1999	Pre-IND meeting	
August 12, 1999	IND filing date	400 mg and 200 mg tablets
February 23, 2000	GI safety meeting	
May 9, 2000	End of Phase 2 meeting	
December 7, 2001	Arthritis Advisory Committee	TARGET study design presented
December 13, 2001	Pre-NDA meeting	Novartis and FDA
April 30, 2002	Trade name consult Prexige	DMETS Recommended against Prexige
November 20, 2002	NDA filing date	Indication- symptomatic relief in the treatment osteoarthritis and rheumatoid arthritis; relief of acute pain; treatment of primary dysmenorrhea
September 2, 2003	DSMB interim analysis	Discussed hepatoxicity, GI, and cardiovascular adverse events
September 23, 2003	NDA Action date	Non approval for inadequate information, facilities, and extablished name not in compliance with USAN.
June 25, 2005	Special Protocol Assessment	SPA for 100 mg efficacy in hip and knee OA. Finally accepted December 2004.
July 1, 2004	TARGET study report submitted to IND	
October 31, 2004	Trade name consult Prexede	DMETS recommended against Prexede. DDAMC accepts Prexede.